

longer period as may be required by the Administrator.

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## PART 117—ANIMALS AT LICENSED ESTABLISHMENTS

Sec.

117.1 Applicability.

117.2 Animal facilities.

117.3 Admittance of animals.

117.4 Test animals.

117.5 Segregation of animals.

117.6 Removal of animals.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 38 FR 15499, June 13, 1973, unless otherwise noted.

### § 117.1 Applicability.

(a) All animals used in licensed establishments in the preparation or testing of biological products shall meet the regulations in this subchapter and special requirements as may be prescribed by the Administrator to prevent the preparation, sale, and distribution of worthless, contaminated, dangerous, or harmful biological products.

(b) Unless otherwise authorized or directed by the Administrator, animals used in the preparation or testing of biological products shall be admitted to and maintained at the licensed establishment and ultimately disposed of in accordance with the regulations in this part, and with the Act of August 24, 1966 (Pub. L. 89–544) as amended by the Animal Welfare Act of 1970 (Pub. L. 91–579) and the regulations in parts 1, 2, and 3 of this chapter. Personnel who supervise the care and welfare of such animals shall be qualified by education, training, and experience to carry out the regulations in this part.

[38 FR 15499, June 13, 1973, as amended at 56 FR 66784, Dec. 26, 1991]

### § 117.2 Animal facilities.

Animal facilities shall comply with the requirements provided in part 108 of this chapter.

### § 117.3 Admittance of animals.

(a) No animal which shows clinical signs or other evidence of disease shall be admitted to the premises of licensed establishments, except as provided in paragraphs (d) and (e) of this section. The health status of all animals offered for admission shall be determined by or under the direction of a veterinarian prior to admission. If the determination cannot be made prior to admission, the animals shall be kept separate from animals already on the premises and in a quarantine area to be provided by the licensee for this purpose until the animal's health status is determined.

(b) If special test requirements for admittance of the animals are specified in the Outline of Production for the product to be produced, the animals shall remain in the quarantine area until such tests have been performed and the results obtained. Animals which do not meet the requirements shall not be admitted to the production area or allowed to contact production animals.

(c) All animals admitted to the premises of a licensed establishment shall be permanently identified either collectively or individually by the licensee with tags, marks, or other means acceptable to the Administrator.

(d) When an animal which has a disease is to be used to prepare a biological product for control of such disease, the animal shall be admitted directly to the processing facilities in which the product is to be prepared but shall not be permitted contact with other animals on the premises.

(e) The Administrator may authorize the maintenance of diagnostic facilities at the licensed establishment: *Provided*, That safeguards proposed by the licensee are adequate to prevent diseased or dead animals brought into such facilities from being a threat to biological products prepared in such establishment or to other animals on the premises used in the preparation of biological products.

[38 FR 15499, June 13, 1973, as amended at 56 FR 66784, Dec. 26, 1991]